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Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

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Supplementary Material

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Statistical Analysis Plan

This is the statistical analysis plan for the first analysis of CCC19 registry data.

Version History

Version 1.2 (April 25, 2020)

Multiple imputation and allowance for exploratory analyses added

Version 1.1 (April 23, 2020)

Changes: obesity and morbid obesity collapsed into one factor

Version 1.0 (April 18, 2020)

Condition or disease: COVID-19 and Cancer

Study Design

Study Type:	Observational Retrospective Chart Review
Data Entry Start Date:	March 17, 2020
Data Entry Complete Date:	April 16, 2020
Sampling method:	Convenient Non-Probability sampling

Groups and Cohort

Primary Group
Adult cancer survivors

Subgroups

Laboratory-confirmed COVID-19 cases

Presumptive cases

Outcome Measures

Primary Outcome Measures:

1. All-cause mortality [Time Frame: within 30 days post COVID-19 diagnosis]

Secondary Outcome Measures:

1. Severe Outcomes – Composite outcome of hospitalized with severe illness/mechanical ventilation /death [Time Frame: within 30 days post COVID-19 diagnosis]
2. Hospitalization during course of COVID-19 illness
3. ICU admission during course of COVID-19 illness
4. Mechanical ventilator use during course of COVID-19 illness
5. Need for supplemental oxygen during course of COVID-19 illness

Eligibility Criteria

Inclusion:
All 3 baseline forms (Demographics, Cancer, COVID-19) completed in REDCap.

Exclusion:

- Age <18 years
- Non-invasive cancers and premalignant conditions
- Non-melanoma skin cancers (e.g. BCC, SCC)
- No laboratory confirmation of COVID-19 (allowed in descriptive analyses)
- Regions outside U.S., Canada, Spain

Missingness
Multiple imputation will be used for categorial variables with a ≤10% rate of missingness. Categorical variables with a >10% rate of missingness will be discarded from the model.

Analyses
After checking for the accuracy, integrity, and distribution of the data, all characteristics and outcomes will be presented using descriptive statistics. We will provide the mean and standard deviation (SD) for normally distributed data and the median and interquartile range (IQR) for asymmetrically distributed data. Counts and percentages will be used to describe the binary and categorical variables. All analyses were performed using R software version 3.6.3 (R Foundation, Vienna, Austria).

The subsections below will describe analyses in addition to the descriptive statistics.

Primary outcome
Null hypothesis: demographic, clinical, biochemical, underlying cancer, and COVID-therapy related variables are not associated with 30-day mortality

Alternative hypothesis: demographic, clinical, biochemical, underlying cancer, and COVID-therapy related variables are associated with 30-day mortality

Data Analysis Plan for the Primary Endpoint: All-cause mortality [Time Frame: within 30 days post COVID-19 diagnosis]

Univariate Analysis Plan for Primary Endpoint

Due to privacy restrictions, dates of COVID-19 diagnosis were collected using intervals (e.g., "diagnosed 2 to 4 weeks ago"). We will use interval-censored time-to-event analysis to analyze the data. For all-cause mortality data analyses, the overall survival time will be estimated using the bootstrap based Kaplan-Meier method with 95% confidence interval (CI). The bootstrap based Rothman CI, which is based on Greenwood's variance, Thomas and Grunkemeier CI, and the simultaneous confidence bands by Nair and Hall and Wellner, will also be reported. The bootstrap based log-rank test will be used to compare the equality of the survival curves.

Multivariable Data Analysis Plan for Primary Endpoint

The strategy used for developing interval-censored Cox proportional hazards (PH) models will involve the following steps: (1) Evaluate the proportional hazards assumptions by a graphical method using a transformation of survival curves; (2) Decide on the allowable complexity of the model (i.e., the number of covariates) based on the effective sample size available; (3) Incorporate pre-specified interactions; The adjusted p-values as well as the adjusted 95% confidence intervals from the interval-censored Cox PH model will be reported.

Sample Size Justification and Precision Analyses

The sample size justification is completed using the computer simulation method for interval-censored data. We assume the survival curve in this study follows the exponential distribution with ≈ 10% loss to follow-up within 30 days. We simulated 2,000 times for each condition. With the proposed sample size, i.e., 920 – 1,000, the half-width of the 95% bootstrap-based Greenwood's Confidence Interval (CI) is less than 2·5%. Therefore, the precision of the overall 30-day mortality of this study is excellent.

A Priori Variables of Interest
In no order of importance:

Possibly include in multivariable model (reference factor is bolded)

i. Age
ii. Sex (M, **F**)
iii. Race/Ethnicity combined (**Non-Hispanic white**, Non-Hispanic black, Hispanic, Other)

iv. Number of major comorbidities (**0**, 1, 2, 3, 4+)

v. ECOG performance status (**0-1**, 2, 3/4, unknown)

vi. Tumor type (**solid**, heme, multiple, unknown)

vii. Active cancer therapy within 4 weeks prior to COVID diagnosis (**no**, active cytotoxic, active non-cytotoxic, active unknown)

viii. Surgery within 4 weeks prior to COVID diagnosis (yes, **no**, unknown)

ix. Cancer status at the time of COVID diagnosis (**remission/NED**, active non-progressing, active progressing, status unknown)

x. Anti-COVID-19 therapy (hydroxychloroquine alone, azithromycin alone, both, **neither**)

xi. Smoking (**never**, former, current, unknown)

xii. Obesity (**not specified**, obese, ~~morbidly obese~~)

xiii. Regions (**U.S. Region 1 [Northeast]**, Region 2 [Midwest], Region 3 [South], Region 4 [West], Canada, Spain)

Specific Interactions

1. Age*comorbidities
2. Race/Ethnicity*Obesity

Secondary Outcomes
Only presented as descriptive statistics. Hypothesis testing statistical tests will not be conducted.

Appendix
1. REDCap data dictionary (**Supplementary Table S1**)
2. Derived variables (**Supplementary Table S2**)

Additional Considerations

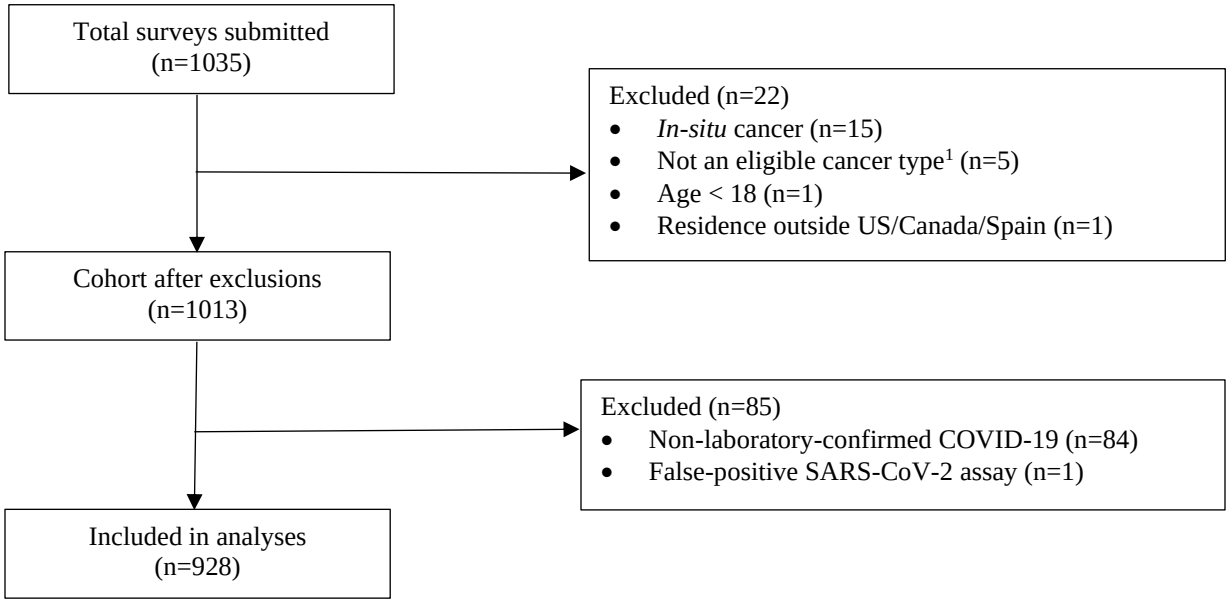
Ordinal Scale defined as: Death; Hospitalized on invasive mechanical ventilation or ECMO (extracorporeal membrane oxygenation); Hospitalized on non-invasive ventilation or high flow nasal cannula; Hospitalized on supplemental oxygen; Hospitalized not on supplemental oxygen; Not hospitalized with limitation in activity (continued symptoms); Not hospitalized without limitation in activity (no symptoms) was considered but will not be evaluated in this current study. Incomplete follow-up for more than half of the cohort and low sample sizes for multiple categories were the primary reasons to not evaluate this scale which would lead to high degree of variability in outcome scoring.

Data-driven multivariable modeling with allowance for nonlinear predictor effects using regression splines, adjustment of variance-covariance matrix for multiple imputation, assessment of the clinical utility (discrimination ability) of the model, internal validation of the calibration and discrimination of the model using bootstrap approaches to estimate the model's likely performance on a new set of samples and application of the elastic net regularized survival analysis to examine the shrinkage of the coefficients were considered. However, given the early follow-up of this report and the still limited amount of degrees of freedom for a multivariable analysis, we favored the primary approach of a very focused previously proposed hypothesis-driven multivariable model with selected *a priori* pre-specified variables and interaction terms with known prior clinical and biological significance. Data-driven methods were considered for exploratory analyses.

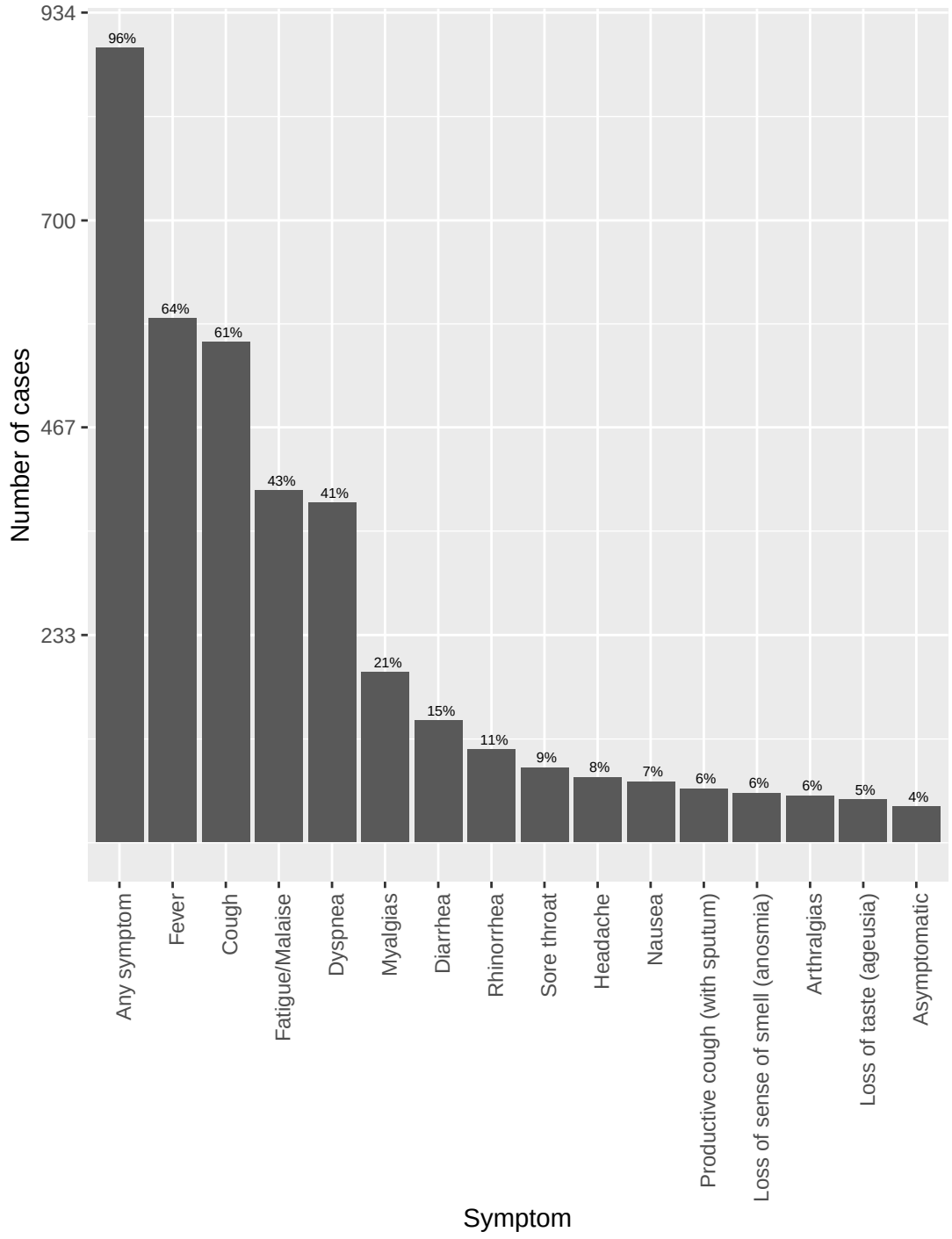
Post-hoc Power Analysis

A *post-hoc* power analysis based on 2,000 computer simulations with 80% power and a two-sided type I error of 5% was conducted to evaluate the effect size of odds ratio (OR) in the logistic regression model. Based on the observed data, i.e., **Surgery** (No: 108 deaths out of 811 study subjects, Yes: 6 deaths out of 32 study subjects, Unknown: 4 deaths out of 42 study subjects). With a sample size of 885 (No = 811, Yes = 32, and Unknown = 42), the estimated odds ratios are 3.14 and 2.87 for Yes vs. No and Unknown vs. No, respectively. Similarly, for **Type of anti-cancer therapy** (None: 75 deaths out of 553 study subjects, Cytotoxic: 22 deaths out of 160 study subjects, Non-cytotoxic: 23 deaths out of 206 study subjects, Unknown: 1 deaths out of 9 study subjects), with a sample size of 928 (None = 553, Cytotoxic = 160, Non-cytotoxic = 206, and Unknown = 9), the estimated odds ratios are 0.40 or 1.89 for Cytotoxic vs. None and 0.44 or 1.82 for Non-cytotoxic vs. None. Therefore, based on the post-hoc power analysis, the effect sizes are reasonable and clinically meaningful.

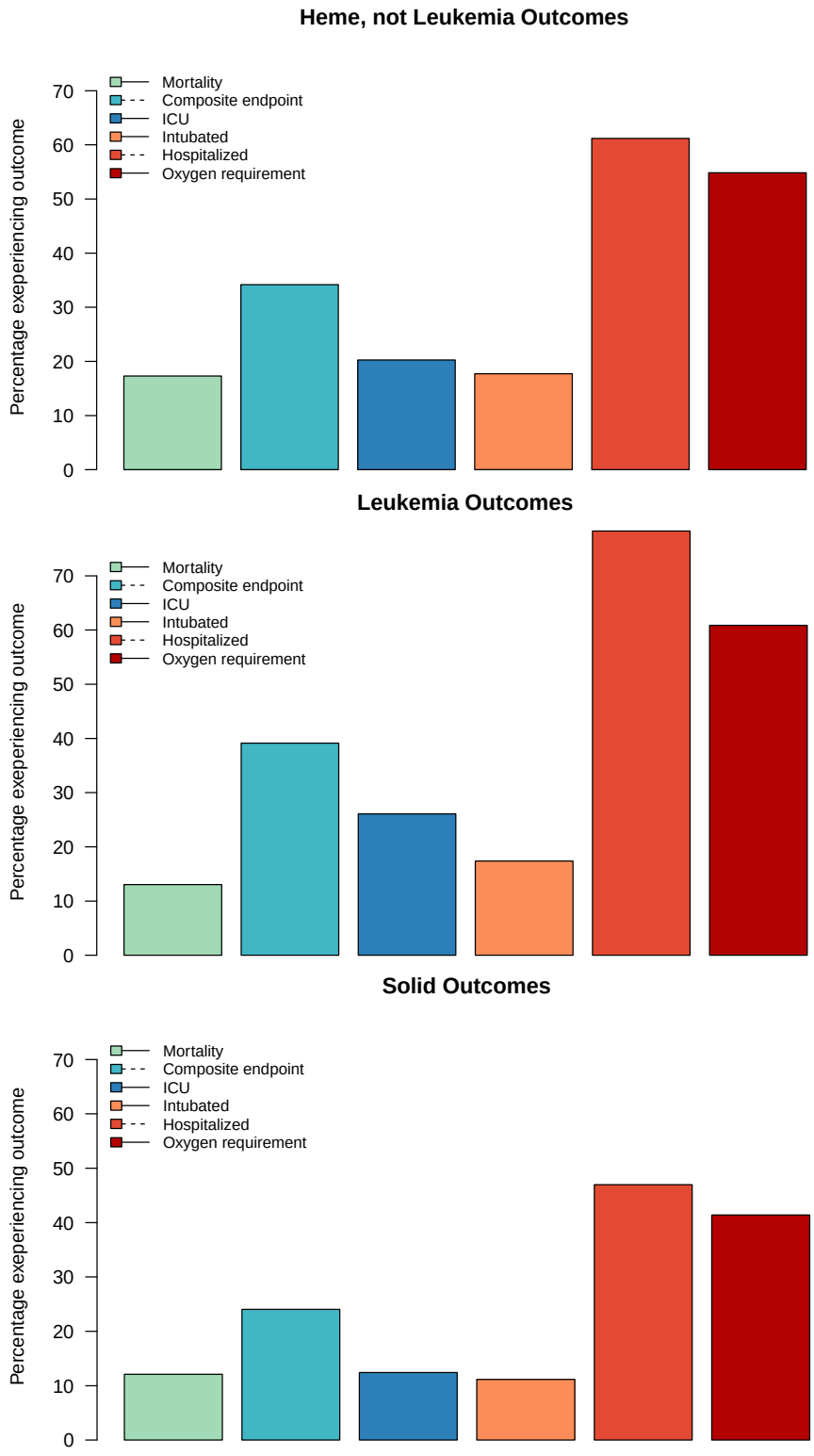
Supplementary Figure S1: CONSORT diagram



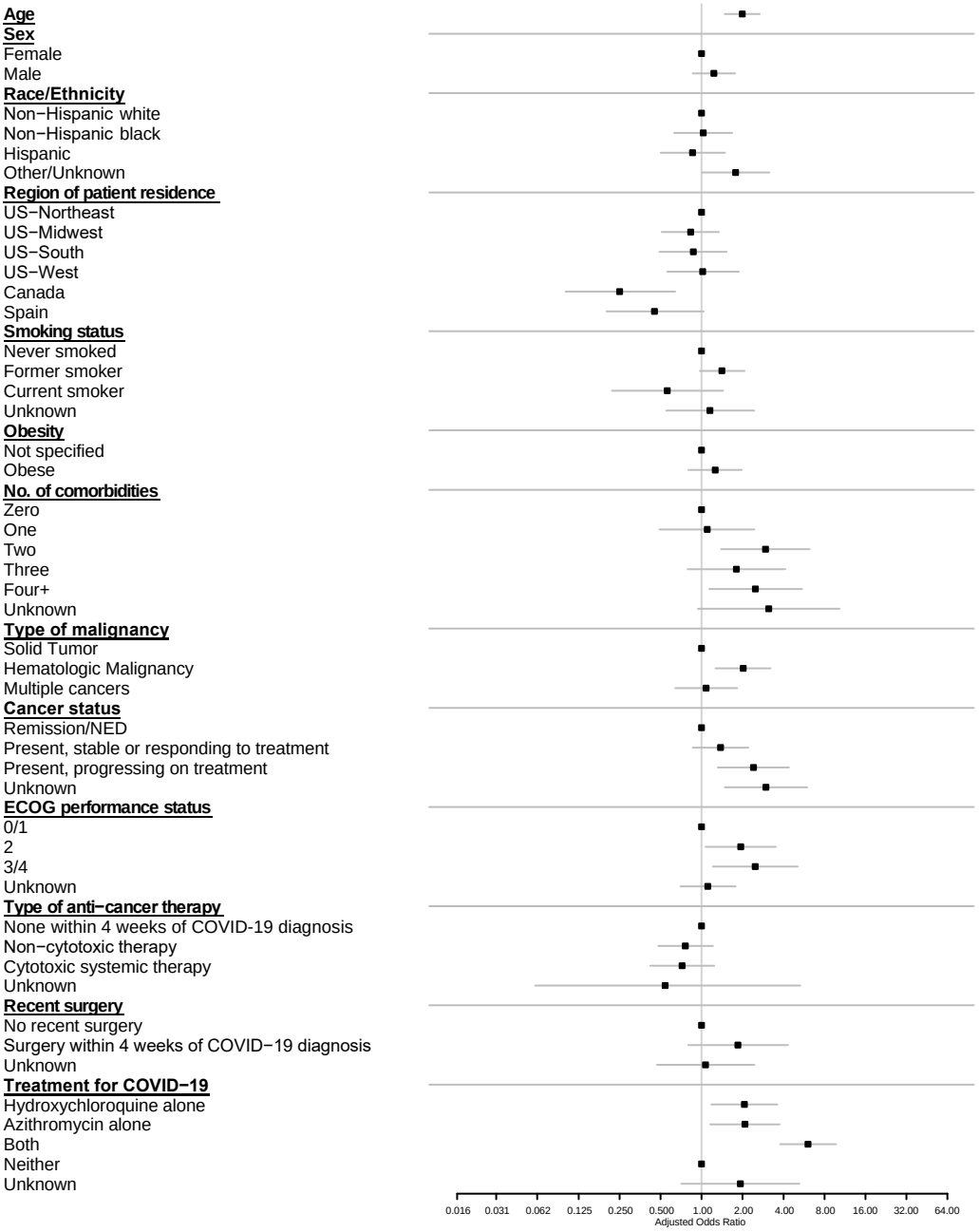
Supplementary Figure S2: Symptoms occurring in more than 5% of patients plus asymptomatic cases.



Supplementary Figure S3: Outcomes as function of primary cancer type.



Supplementary Figure S4: Forest plot of factors associated with composite of severe illness. Severe illness is defined as death, severe illness requiring hospitalization, intensive care unit admission, and/or mechanical ventilation.



Supplementary Table S1: Data elements in the CCC19 data collection form. Note that the survey contains extensive branching logic; not every patient will have every one of these elements completed. ABNL: abnormal (outside normal reference range); ATC: Anatomical Therapeutic Classification; HI: above normal reference range; LO: below normal reference range; N: No; NA: not applicable; NAACCR: North American Association of Central Cancer Registries; NCIT: National Cancer Institute Thesaurus; OMOP: Observational Medical Outcomes Partnership Data Model; PHIN VADS: Public Health Information Network Vocabulary Access and Distribution System; SNOMED-CT: Systematized Nomenclature of Medicine, Clinical Terms; UNK: Unknown; WNL: within normal limits; Y: Yes

Variable Name	Description	Value Set or Terminology	Category
aspirin_dose		SNOMED-CT	Baseline clinical details
bl_anticoag_reason	Why anticoagulation at baseline?	SNOMED-CT	Baseline clinical details
bl_anticoag_type	Anticoagulation at baseline?	ATC	Baseline clinical details
blood_type	ABO blood type	Direct coding + UNK	Baseline clinical details
blood_type_rh	Rh blood type	Direct coding + UNK	Baseline clinical details
comorbid_no	number of comorbidities	Integer + UNK	Baseline clinical details
concomitant_meds	Medications being taken at presentation	ATC	Baseline clinical details
ecog_status		Direct coding + UNK	Baseline clinical details
gcsf	G-CSF within 2 weeks of diagnosis?	Y/N/UNK	Baseline clinical details
influenza_vax	Seasonal flu vaccine?	Y/N/UNK	Baseline clinical details
o2_requirement	Baseline supplemental oxygen requirement?	Y/N/UNK	Baseline clinical details
recent_surgery		Y/N/UNK	Baseline clinical details
significant_comorbidities		SNOMED-CT	Baseline clinical details
smoking_product	Type of tobacco product	SNOMED-CT	Baseline clinical details
smoking_status		Custom	Baseline clinical details
steroid_specific_2	Steroid dosing	Custom	Baseline clinical details
surgery_timing		Custom	Baseline clinical details
cancer_status		Custom	Cancer details
cancer_timing		Custom	Cancer details
cancer_type	Primary malignancy type	NCIT	Cancer details
cancer_type_2	2nd malignancy type (if applicable)	NCIT	Cancer details
clinical_trial	On a cancer clinical trial?	Y/N/UNK	Cancer details
hx_treatment	Timing of cancer treatment	Custom	Cancer details
intravesicular_bcg		Y/N/UNK	Cancer details
irae_past	History of immune-related adverse (irAE) event?	Y/N/UNK	Cancer details
multiple_ca	Multiple malignancies?	Y/N/UNK	Cancer details
on_treatment	On recent cancer treatment	Y/N/UNK	Cancer details
other_irae	Other immune-related adverse event?	Y/N/UNK	Cancer details
pneumonitis	Concurrent irAE pneumonitis?	Custom	Cancer details
prior_tx	prior lung-toxic therapy?	HemOnc	Cancer details
radiotherapy	Lung-directed radiation in the past?	Y/N/UNK	Cancer details

Variable Name	Description	Value Set or Terminology	Category
recent_treatment	Most recent anti-cancer treatment	Custom	Cancer details
stage	Cancer stage	NAACCR	Cancer details
transplant_cellular_therapy		Custom	Cancer details
transplant_cellular_timing		Custom	Cancer details
treatment_context		HemOnc	Cancer details
treatment_intent		Custom	Cancer details
treatment_modality		HemOnc	Cancer details
what_immunotherapy		HemOnc	Cancer details
berlin_2	Berlin criteria if ARDS	Direct coding + UNK	COVID-19 details
berlin_yn	Berlin criteria collected?	Y/N/UNK	COVID-19 details
c19_anticoag_reason	Purpose of anticoagulation	Custom	COVID-19 details
c19_anticoag_type	Type of anticoagulant used	ATC	COVID-19 details
c19_aspirin_dose		SNOMED-CT	COVID-19 details
c19_bleeding		SNOMED-CT-modified	COVID-19 details
c19_complications_card	Cardiac complications	SNOMED-CT	COVID-19 details
c19_complications_gi	Gastrointestinal complications	SNOMED-CT	COVID-19 details
c19_complications_other		SNOMED-CT	COVID-19 details
c19_complications_pulm	Pulmonary complications	SNOMED-CT	COVID-19 details
c19_complications_systemic		SNOMED-CT	COVID-19 details
coinfection		SNOMED-CT	COVID-19 details
coinfection_yn		Y/N/UNK	COVID-19 details
complications_severity		Custom	COVID-19 details
covid_19_diagnosis	How was diagnosis of COVID-19 made?	Custom	COVID-19 details
covid_19_dx_interval	Time since COVID-19 diagnosis	Custom	COVID-19 details
covid_19_treatment		ATC/HemOnc/OMOP/RxNorm	COVID-19 details
covid_19_treatment_trial	Any COVID-19 treatment on trial?	Y/N/UNK	COVID-19 details
covid_19_trial_tx	Treatment(s) on trial	ATC/HemOnc/OMOP/RxNorm	COVID-19 details
covid_19_tx_interleukin	Anti-interleukin treatments	ATC	COVID-19 details
covid_19_tx_tnf	TNF-alpha treatments	ATC	COVID-19 details
current_status	ADT status	Custom	COVID-19 details
current_status_clinical	Clinical status	Custom	COVID-19 details
current_status_retro	Clinical status	Custom	COVID-19 details
current_status_v2	Clinical status	Custom	COVID-19 details
days_to_death		Integer	COVID-19 details
dx_year	year of COVID-19 diagnosis	Integer	COVID-19 details
hosp_los	Floor length of stay (LOS)	Integer, days	COVID-19 details
hosp_los_2	Floor LOS if transferred to ICU	Integer, days	COVID-19 details
hosp_status		Custom	COVID-19 details

Variable Name	Description	Value Set or Terminology	Category
icu_los	ICU length of stay	Integer, days	COVID-19 details
mortality	30-day mortality status	Y/N/NA/UNK	COVID-19 details
neg_test	was initial COVID-19 test negative	Y/N/UNK	COVID-19 details
o2_policy	Policy on intubation?	Y/N/UNK	COVID-19 details
o2_requirement_c19	Supplemental O2 needed?	Y/N/UNK	COVID-19 details
prbc	PRBC transfusions given?	Y/N/UNK	COVID-19 details
resp_failure_tx	Treatments for respiratory failure	Custom	COVID-19 details
sepsis_pressors	Pressors for sepsis or HoTN?	Y/N/UNK	COVID-19 details
severity_of_covid_19		Custom	COVID-19 details
steroid_specific	Steroid dosing	Custom	COVID-19 details
symptoms		SNOMED-CT	COVID-19 details
timing_of_report	Real-time or retrospective?	Custom	COVID-19 details
worst_complications_severity	Retrospective worst complications	Custom	COVID-19 details
worst_status_clinical	Retrospective worst clinical status	Custom	COVID-19 details
age	Age in decade intervals	Custom	Demographics
age_exact	Age in years	Integer	Demographics
bcg_vax	History of BCG vaccine?	Y/N/UNK	Demographics
city	city of healthcare delivery	NA (free text)	Demographics
country_of_patient_residen		Custom	Demographics
ethnicity		PHIN VADS	Demographics
facility		NA (free text)	Demographics
gender	Sex or gender of patient	Custom	Demographics
hcw	health care worker	Y/N/UNK	Demographics
race		PHIN VADS	Demographics
state_of_patient_residence		Direct coding (US abbreviations)	Demographics
berlin_fu	Berlin criteria if ARDS	Direct coding + UNK	Follow-up details
berlin_yn_fu	Berlin criteria collected?	Y/N/UNK	Follow-up details
c19_addl_treatment		Y/N/UNK	Follow-up details
c19_anticoag_reason_fu	Purpose of anticoagulation	Custom	Follow-up details
c19_anticoag_type_fu	Type of anticoagulant used	ATC	Follow-up details
c19_aspirin_dose_fu		SNOMED-CT	Follow-up details
c19_bleeding_fu		SNOMED-CT-modified	Follow-up details
c19_complications_card_fu		SNOMED-CT	Follow-up details
c19_complications_gi_fu		SNOMED-CT	Follow-up details
c19_complications_other_fu		SNOMED-CT	Follow-up details
c19_complications_pulm_fu		SNOMED-CT	Follow-up details
c19_complications_systemic_fu		SNOMED-CT	Follow-up details
cancer_tx_fu	Was treatment modified due to COVID-19?	Y/N/UNK	Follow-up details

Variable Name	Description	Value Set or Terminology	Category
complications_severity_fu		Custom	Follow-up details
covid_19_status_fu		Custom	Follow-up details
covid_19_treatment_fu		ATC/HemOnc/OMOP/RxNorm	Follow-up details
covid_19_treatment_trial_fu		Y/N/UNK	Follow-up details
covid_19_trial_tx_fu		ATC/HemOnc/OMOP/RxNorm	Follow-up details
covid_19_tx_interleukin_fu		ATC	Follow-up details
covid_19_tx_tnf_fu		ATC	Follow-up details
current_status_clinical_fu		Custom	Follow-up details
current_status_fu		Custom	Follow-up details
days_to_death_fu		Integer	Follow-up details
fu_weeks		Numeric, weeks	Follow-up details
hosp_los_fu		Integer, days	Follow-up details
hosp_los_fu_2		Integer, days	Follow-up details
hosp_status_fu		Y/N/UNK	Follow-up details
hotn_pressors_fu		Y/N/UNK	Follow-up details
icu_los_fu		Integer, days	Follow-up details
o2_requirement_fu		Y/N/UNK	Follow-up details
resp_failure_tx_fu		Custom	Follow-up details
steroid_specific_fu	Steroid dosing	Custom	Follow-up details
timing_of_report_weeks		Numeric, weeks	Follow-up details
aec	absolute eosinophil count	Numeric, per uL	Laboratory values
aec_range	absolute eosinophil count	LO/WNL/HI/UNK	Laboratory values
alc	absolute lymphocyte count	Numeric, per uL	Laboratory values
alc_range	absolute lymphocyte count	LO/WNL/HI/UNK	Laboratory values
alt	Alanine aminotransferase	NL/ABNL/UNK	Laboratory values
alt_numeric	Alanine aminotransferase	Numeric, units/L	Laboratory values
anc	absolute neutrophil count	Numeric, per uL	Laboratory values
anc_range	absolute neutrophil count	LO/WNL/HI/UNK	Laboratory values
aptt	activated partial thromboplastin time	NL/ABNL/UNK	Laboratory values
aptt_numeric	activated partial thromboplastin time	Numeric, s	Laboratory values
ast	Aspartate aminotransferase	NL/ABNL/UNK	Laboratory values
ast_numeric	Aspartate aminotransferase	Numeric, units/L	Laboratory values
bnp	Brain natriuretic peptide	NL/ABNL/UNK	Laboratory values
bnp_numeric	Brain natriuretic peptide	Numeric, pg/mL	Laboratory values
creat	Serum creatinine	NL/ABNL/UNK	Laboratory values
creat_numeric	Serum creatinine	Numeric, mg/dL	Laboratory values
crp	C-reactive protein	NL/ABNL/UNK	Laboratory values
crp_numeric	C-reactive protein	Numeric, specify units	Laboratory values

Variable Name	Description	Value Set or Terminology	Category
ddimer	D-Dimer	NL/ABNL/UNK	Laboratory values
ddimer_numeric	D-Dimer	Numeric, specify units	Laboratory values
fibrinogen		NL/ABNL/UNK	Laboratory values
fibrinogen_numeric		Numeric, mg/dL	Laboratory values
hgb	hemoglobin	Numeric, g/dL	Laboratory values
hgb_range	hemoglobin	LO/WNL/HI/UNK	Laboratory values
hs_trop	high-sensitivity troponin	NL/ABNL/UNK	Laboratory values
hs_trop_numeric	high-sensitivity troponin	Numeric, pg/mL	Laboratory values
il6	Interleukin-6 level	NL/ABNL/UNK	Laboratory values
il6_numeric	Interleukin-6 level	Numeric, pg/mL	Laboratory values
ldh	lactate dehydrogenase	NL/ABNL/UNK	Laboratory values
ldh_numeric	lactate dehydrogenase	Numeric, specify units	Laboratory values
other_lab		NL/ABNL/UNK	Laboratory values
plt	Platelet count	Numeric, per 10^3/uL	Laboratory values
plt_range	Platelet count	LO/WNL/HI/UNK	Laboratory values
pt	prothrombin time	NL/ABNL/UNK	Laboratory values
pt_numeric	prothrombin time	Numeric, s	Laboratory values
tbili	total bilirubin	NL/ABNL/UNK	Laboratory values
tbili_numeric	total bilirubin	N/A (free text)	Laboratory values
tni	tropnonin I	NL/ABNL/UNK	Laboratory values
tni_numeric	tropnonin I	Numeric, ng/mL	Laboratory values
wbc_numeric	White blood cell count	Numeric, per 10^9/L	Laboratory values
wbc_range	White blood cell count	LO/WNL/HI/UNK	Laboratory values
ccc19	Participating site of CCC19?	Y/N	Metadata
ccc19_institution	Identifier of CCC19 site	Integer	Metadata
patient_id	CCC19 institution non-PHI ID	Integer	Metadata
record_id	Automatic numbering	Integer	Metadata
practice_setting		Custom	Respondent details
role	primary managing hematologist or oncologist?	Y/N	Respondent details
role_2	expand if role = N	Custom	Respondent details

Supplementary Table S2: Derived variables. In order to conduct the analysis, transformations were necessary to create derived variables. Raw variable names are shown in italics and are described in Supplementary Table S1. Rules are applied in order.

Derived variable name	Description
Age	1. If *age_exact* exists, keep 2. If *age_exact* does not exist and *age* equals "Older than 90" → 90 3. If *age_exact* does not exist and *age* equals "18-29", "30-39", "40-49", "50-59", "60-69", "70-79", or "80-89" → take the midpoint of the age interval as the age
Sex	1. If *gender* equals female, keep 2. If *gender* equals male, keep 3. If *gender* equals other or prefer not to say → unknown
Race/ethnicity	1. If *race* has white checked AND *ethnicity* equals NOT Hispanic or Latino OR unknown/not reported → White non-Hispanic 2. If *race* has black or African American checked AND *ethnicity* equals NOT Hispanic or Latino OR unknown/not reported → Black non-Hispanic 3. Any other *race* choice is assigned → Other/Unknown 4. If *ethnicity* equals Hispanic or Latino → Hispanic
Region of patient residence	1. If *state_of_patient_residence* equals ME, NH, VT, MA, RI, CT, PA, NY, or NJ → US-Northeast 2. If *state_of_patient_residence* equals WI, MI, IL, IN, OH, MO, ND, SD, NE, KS, MN, or IA → US-Midwest 3. If *state_of_patient_residence* equals DE, MD, DC, VA, WV, NC, SC, GA, FL, TN, KY, MS, AL, OK, TX, LA, or AR → US-South 4. If *state_of_patient_residence* equals ID, MT, WY, NV, UT, CO, AZ, NM, AK, WA, OR, CA, or HI → US-West 5. If *country_of_patient_residence* equals Canada, keep 6. If *country_of_patient_residence* equals Spain, keep 7. If *country_of_patient_residence* equals any other except US, exclude
Smoking status	1. If *smoking_status* equals never smoker, keep 2. If *smoking_status* equals current smoker, keep 3. If *smoking_status* equals unknown, keep 4. If *smoking_status* equals "former smoker, NOS" OR "former smoker, quit less than 1 year ago" OR "former smoker, quit between 1 and 5 years ago" OR "former smoker, quit between 6 and 10 years ago" OR "former smoker, quit more than 10 years ago" → former smoker
Obesity	1. If *significant_comorbidities* has obesity OR morbid obesity checked → Obese 2. If *significant_comorbidities* does not have either obesity or morbid obesity checked AND has at least one other choice checked → Not specified 3. If *significant_comorbidities* does not have any choices checked → Missing
No. of comorbidities	Direct variable (no transformation)
Type of malignancy **Note**: these values are coded according to the NCI thesaurus.	1. If *cancer_type* equals "C8851", "C3209", "C9244", "C3167", "C3163", "C9308", "C4341", "C3211", "C9357", "C4337", "C2912", "C8504", "C27908", "C3247", "C3171", "C4345", "C3106", "C3174", "C3242", "C4665", "C3819", "C9300", or "C27134" AND *cancer_type_2* does not have data → hematologic malignancy 2. If *cancer_type* does NOT equal "C8851", "C3209", "C9244", "C3167", "C3163", "C9308", "C4341", "C3211", "C9357", "C4337", "C2912", "C8504", "C27908", "C3247", "C3171", "C4345", "C3106", "C3174", "C3242", "C4665", "C3819", "C9300", or "C27134" AND *cancer_type_2* does not have data → solid tumor 3. If cancer_type equals "OTH" AND *cancer_type_2* does not have data AND free text description *cancer_type_oth* is not sufficient to assign to hematologic or solid tumor → unknown 4. If *cancer_type_2* has any data → multiple
Cancer status	1. If *cancer_status* equals "remission/NED", keep 2. If *cancer_status* equals "active disease, responding to treatment" OR "active disease, stable" → present, stable or responding to treatment 3. If *cancer_status* equals "active disease, progressing", keep 4. If *cancer_status* equals "unknown", keep
ECOG performance status	1. If *ecog_status* equals 0 or 1 → 0/1 2. If *ecog_status* equals 2, keep 3. If *ecog_status* equals 3 or 4 → 3/4 4. If *ecog_status* equals unknown, keep
Type of anti-cancer therapy	1. If *on_treatment* equals No → None 2. If *on_treatment* equals Yes AND *recent_treatment* equals "within the month to 3 months prior to COVID-19 diagnosis" OR "more than 3 months prior to COVID-19 diagnosis" → None 3. If *treatment_modality* has "Immunotherapy", "Targeted therapy", "Endocrine therapy", "Radiotherapy", "Transplant/Cellular therapy", "Intravesicular therapy (e.g., BCG)" or

	"Other" checked AND *recent_treatment* equals "less than 2 weeks prior to COVID-19 diagnosis" OR "within 2 to 4 weeks prior to COVID-19 diagnosis" → Non-cytotoxic 4. If *treatment_modality* has "Cytotoxic chemotherapy" checked AND *recent_treatment* equals "less than 2 weeks prior to COVID-19 diagnosis" OR "within 2 to 4 weeks prior to COVID-19 diagnosis" → Cytotoxic 5. If *on_treatment* equals unknown OR *recent_treatment* equals unknown → Unknown 6. If *on_treatment* equals Yes AND *recent_treatment* does not have data → Unknown
Recent surgery	1. If *recent_treatment* equals "less than 2 weeks prior to COVID-19 diagnosis" OR "within 2 to 4 weeks prior to COVID-19 diagnosis" AND *treatment_modality* has surgery checked → Yes 2. If *recent_surgery* equals Yes AND *surgery_timing* equals "within the past month" → Yes 3. If *recent_treatment* equals "within the month to 3 months prior to COVID-19 diagnosis" OR "more than 3 months prior to COVID-19 diagnosis" AND *treatment_modality* has surgery checked → No 4. If *recent_surgery* equals Yes AND *surgery_timing* equals "within the past month" → No 5. If *recent_surgery* equals No, keep 6. If *recent_treatment* equals "unknown" AND *treatment_modality* has surgery checked → unknown 7. If *recent_surgery* equals Unknown, keep
Treatment of COVID-19	1. If *covid_19_treatment* OR *covid_19_trial_tx* OR *covid_19_treatment_fu* OR *covid_19_trial_tx_fu* has hydroxychloroquine checked AND azithromycin unchecked → hydroxychloroquine alone 2. If *covid_19_treatment* OR *covid_19_trial_tx* OR *covid_19_treatment_fu* OR *covid_19_trial_tx_fu* has hydroxychloroquine unchecked AND azithromycin checked → azithromycin alone 3. If *covid_19_treatment* OR *covid_19_trial_tx* OR *covid_19_treatment_fu* OR *covid_19_trial_tx_fu* has hydroxychloroquine checked AND azithromycin checked → both 4. If *covid_19_treatment* OR *covid_19_trial_tx* OR *covid_19_treatment_fu* OR *covid_19_trial_tx_fu* has hydroxychloroquine unchecked AND azithromycin unchecked AND unknown unchecked → neither 5. If *covid_19_treatment* OR *covid_19_trial_tx* OR *covid_19_treatment_fu* OR *covid_19_trial_tx_fu* has hydroxychloroquine unchecked AND azithromycin unchecked AND unknown checked → unknown 6. If these fields have no options checked → Missing
Death (binary outcome variable) **Note:** for the primary outcome analysis, timestamp metadata is combined with *covid_19_dx_interval* to determine whether the death occurred within a 30-day window	1. If *current_status_retro* equals "Died" or *current_status_v2* equals "Died" or *current_status* equals "None – patient is deceased" → Yes 2. If *current_status_retro* NOT equals "Died" AND *current_status_v2* NOT equals "Died" AND *current_status* NOT equals "None – patient is deceased" → No 3. If *covid_19_status_fu* equals "Died" or *current_status_fu* equals "None – patient is deceased" or *fu_reason* equals "Death" → Yes 4. If none of the above are met → Unknown
ICU admission (binary outcome variable)	1. If *hosp_status* OR *hosp_status_fu* equals "Yes – admitted to floor and then transferred to the ICU" or "Yes – admitted directly to the ICU" → Yes 2. If *current_status* OR *current_status_fu* equals "ICU – new admit" or "ICU – continued" → Yes 3. If *worst_status_clinical* OR *current_status_clinical* OR *current_status_clinical_fu* equals "Critical (ICU) – Severely ill, not requiring ventilator support" or "Critical (ICU) – Severely ill, intubated" → Yes
Mechanical ventilation (binary outcome variable)	1. If *resp_failure_tx* equals "Intubation" → Yes 2. If *worst_status_clinical* OR *current_status_clinical* OR *current_status_clinical_fu* equals "Critical (ICU) – Severely ill, intubated" → Yes
Hospitalization (binary outcome variable)	1. If *hosp_status* OR *hosp_status_fu* equals "Yes – admitted to floor for the duration of the illness", "Yes – admitted to floor and then transferred to the ICU", or "Yes – admitted directly to the ICU" → Yes 2. If *current_status* OR *current_status_fu* equals "Hospitalized (non-ICU) – new admit", "Hospitalized (non-ICU) – continued", "ICU – new admit", or "ICU – continued" → Yes 3. If *worst_status_clinical* OR *current_status_clinical* OR *current_status_clinical_fu* equals "Inpatient – Moderately ill", "Inpatient – Severely ill", "Critical (ICU) – Severely ill, not requiring ventilator support", or "Critical (ICU) – Severely ill, intubated" → Yes 4. If *c19_anticoag_reason* OR *c19_anticoag_reason_fu* has "For DIC during hospitalization" checked → Yes
Supplemental oxygen (binary outcome variable)	1. If *o2_requirement* OR *o2_requirement_c19* OR *o2_requirement_fu* equals Yes → Yes 2. If *resp_failure_tx* or *resp_failure_tx_fu* has data → Yes
Composite severe outcome (binary outcome variable)	1. If Death equals Yes → Yes 2. If ICU admission equals Yes → Yes

	3. If Mechanical ventilation equals Yes → Yes 4. If *worst_status_clinical* OR *current_status_clinical* OR *current_status_clinical_fu* equals "Inpatient – Severely ill" → Yes

Supplementary Table S3: Baseline characteristics and outcomes of cases not reported as laboratory-confirmed

	Cases, n (%)
Total	84 (100)
Age – yr	
Median (IQR)	67 (59-76)
Range	18-90
Sex	
Female	41 (49)
Male	43 (51)
Race/ethnicity – no. (%)	
Non-Hispanic white	47 (56)
Non-Hispanic black	8 (10)
Hispanic	20 (24)
Other	6 (7)
Missing	3 (4)
Region of patient residence – no. (%)	
US-Northeast	40 (48)
US-Midwest	7 (8)
US-South	24 (29)
US-West	9 (11)
Canada	2 (2)
Spain	2 (2)
Smoking status – no. (%)	
Never smoked	31 (37)
Current smoker	4 (5)
Former smoker	39 (46)
Unknown	6 (7)
Missing	4 (5)
Obesity – no. (%)	
Not specified	70 (83)
Obese	8 (10)
Missing	6 (7)
No. of comorbidities – no. (%)	
0	9 (11)
1	18 (21)
2	21 (25)
3	14 (17)
4+	11 (13)
Unknown	6 (7)
Missing	5 (6)
Type of malignancy – no. (%)	
Solid tumors	59 (70)
Hematologic malignancies	18 (21)
Multiple cancers	7 (8)
Cancer status - no. (%)	
Remission/No evidence of disease (NED)	29 (35)
Present, stable or responding to treatment	30 (36)
Present, progressive disease	14 (17)
Unknown	4 (5)
Missing	7 (8)
ECOG performance-status score - no. (%)	
0/1	48 (57)
2	7 (8)
3/4	6 (7)
Unknown	20 (24)
Missing	3 (4)
Type of active cancer therapy - no. (%)	
None in the 4 weeks prior to COVID-19 diagnosis	44 (52)
Non-cytotoxic therapy	24 (29)
Cytotoxic systemic therapy	14 (17)
Unknown	2 (2)
Recent surgery - no. (%)	

	Cases, n (%)
None in the 4 weeks prior to COVID-19 diagnosis	69 (82)
Yes	2 (2)
Unknown	8 (10)
Missing	5 (6)
Treatment of COVID-19 - no. (%)	
Hydroxychloroquine	4 (5)
Azithromycin	9 (11)
Both	8 (10)
Neither	47 (56)
Unknown	8 (10)
Missing	8 (10)
Outcomes – no. (%)	
Deaths	13 (15)
Composite outcome	25 (30)
ICU admission	14 (17)
Intubated	11 (13)
Hospitalized	34 (40)
Required supplemental oxygen	34 (40)

Supplementary Table S4: C-statistics for multivariable logistic regression models.

Model	C-statistic (95% CI)
Base (age, sex, smoking status, obesity)	0·73 (0·69-0·78)
Base + race/ethnicity	0·74 (0·7-0·79)
Base + region of patient residence	0·76 (0·72-0·8)
Base + no· of comorbidities	0·75 (0·71-0·8)
Base + type of malignancy	0·74 (0·69-0·78)
Base + cancer status	0·78 (0·74-0·82)
Base + ECOG performance status	0·77 (0·73-0·82)
Base + active therapy	0·74 (0·69-0·78)
Base + surgery	0·74 (0·69-0·78)
Base + COVID-19 treatment	0·77 (0·73-0·81)
Average	**0·75 (0·71-0·80)**

Supplementary Table S5: Variance inflation factors.

Variable	VIF
Age	1·03
Male sex	1·04
Former smoker	1·17
Current smoker	1·08
Smoking status unknown	1·08
Obese	1·03
Non-Hispanic Black	1·11
Hispanic	1·11
Other race and ethnicity	1·08
US-Midwest region	1·17
US-South region	1·15
US-West region	1·16
Canada region	1·07
Spain region	1·14
One comorbidity	4·40
Two comorbidities	7·86
Three comorbidities	5·77
Four comorbidities	7·30
Unknown comorbidities	2·19
Hematologic malignancy tumor type	1·08
Multiple tumor types	1·07
Cancer status: present, not progressing	1·32
Cancer status: present, progressing	1·36
Cancer status: other or unknown	1·16
ECOG performance status 2	1·16
ECOG performance status 3/4	1·16
ECOG performance status unknown	1·14
Active cytotoxic therapy	1·15
Active noncytotoxic therapy	1·09
Active therapy unknown	1·02
Surgery within 4 weeks of COVID-19 diagnosis	1·00
Recent surgery unknown	1·02
Hydroxychloroquine alone	1·15
Azithromycin alone	1·14
Hydroxychloroquine plus azithromycin	1·25
Anti-COVID-19 treatment unknown	1·08

Supplementary Table S6: Elastic net regularized logistic regression analysis results.
Variable selection results using elastic net regularization with the mixing parameter of 0.5 for multivariable logistic regression model of prognostic factors associated with 30-day all-cause mortality. AOR: adjusted odds ratio.

Characteristic	Multivariable AOR (95% CI)
Age[1]	1.83 (1.49-2.25)
Sex	
Female	Reference
Male	1.82 (1.16-2.86)
Smoking status	
Never smoked/Current smoker/Unknown	Reference
Former smoker	1.77 (1.14-2.73)
Cancer status	
Remission/NED	Reference
Present, stable or responding to treatment / Other	1.59 (0.98-2.60)
Present, progressive disease	4.33 (2.27-8.27)
ECOG performance-status score	
0/1	Reference
2	4.03 (2.18-7.48)
3/4	5.89 (2.82-12.30)
Unknown	1.44 (0.81-2.55)
Treatment of COVID-19	
Neither	Reference
Hydroxychloroquine/Azithromycin/Unknown	1.73 (1.01-2.98)
Both	3.87 (2.30-6.49)

[1]Age 90+ transformed into exact age of 90 for modeling purposes. Reported risks are per decade.

Supplementary Table S7: Characteristics of patients dying with and without ICU admission.

	Deaths with ICU admission, n (%)	Deaths without ICU admission, n (%)
Total	50/121 (41)	71/121 (59)
Age		
< 65	11/25 (44)	14/25 (56)
65-75	12/26 (46)	14/26 (54)
75+	27/70 (39)	43/70 (61)
Region		
Spain	0/10 (0)	10/10 (100)
Non-Spain	50/111 (45)	61/111 (55)
Cancer status[1]		
Remission/No evidence of disease	21/39 (54)	18/39 (46)
Present, stable or responding to treatment	16/41 (39)	25/41 (61)
Present, progressive disease	7/25 (28)	18/25 (72)
Unknown	6/11 (55)	5/11 (45)
Treatment intent[2]		
Curative	6/11 (55)	5/11 (45)
Palliative	15/46 (33)	31/46 (67)

[1]Deaths add up to 116 due to missing data on n=5 patients for this variable
[2]Deaths add up to 57 due to n=60 patients being on treatment, and n=3 patients with unknown treatment intent

Supplementary Table S8: Secondary outcomes of hospitalization and oxygen supplementation.

	Total, n	Hospitalized, n (%)	Ever needed supplemental oxygen, n (%)
Total	928	466 (50)	405 (44)
Age			
< 65	412	153 (37)	129 (31)
65-75	237	125 (53)	108 (46)
75+	279	188 (67)	168 (60)
Sex[1]			
Female	459	209 (46)	185 (40)
Male	468	257 (55)	220 (47)
Race/ethnicity			
Non-Hispanic white	460	222 (48)	209 (45)
Non-Hispanic black	148	87 (59)	72 (49)
Hispanic	150	69 (46)	59 (39)
Other/unknown	128	73 (57)	54 (42)
Missing	42	15 (36)	11 (26)
Region of patient residence			
US-Northeast	375	205 (55)	179 (48)
US-Midwest	203	97 (48)	97 (48)
US-South	117	61 (52)	47 (40)
US-West	116	37 (32)	34 (29)
Canada	49	34 (69)	21 (43)
Spain	68	32 (47)	27 (40)
Smoking status			
Never smoked	469	205 (44)	174 (37)
Former smoker	326	201 (62)	182 (56)
Current smoker	43	25 (58)	19 (44)
Unknown	57	26 (46)	21 (37)
Missing	33	9 (27)	9 (27)
Obesity			
Not specified	720	367 (51)	309 (43)
Obese	172	85 (49)	87 (51)
Missing	36	14 (39)	9 (25)
No. of comorbidities			
0	132	28 (21)	25 (19)
1	202	77 (38)	57 (28)
2	231	133 (58)	123 (53)
3	117	70 (60)	55 (47)
4+	192	137 (71)	122 (64)
Unknown	23	13 (57)	13 (57)
Missing	31	8 (26)	10 (32)
Type of malignancy			
Solid tumors	654	301 (46)	261 (40)
Hematologic malignancies	167	104 (62)	89 (53)
Multiple cancers[3]	107	61 (57)	55 (51)
Cancer status			
Remission/no evidence of disease (NED)	422	207 (49)	180 (43)
Present, stable or responding to treatment	294	149 (51)	133 (45)
Present, progressive disease	102	62 (61)	49 (48)
Unknown	59	26 (44)	23 (39)
Missing	51	22 (43)	20 (39)
ECOG performance status			
0/1	614	281 (46)	238 (39)
2	72	52 (72)	42 (58)
3/4	46	32 (70)	30 (65)
Unknown	167	94 (56)	87 (52)
Missing	29	7 (24)	8 (28)
Type of anti-cancer therapy			
None in the 4 weeks prior to COVID-19 diagnosis	553	290 (52)	254 (46)
Non-cytotoxic therapy	206	94 (46)	86 (42)
Cytotoxic systemic therapy	160	81 (51)	63 (39)
Unknown	9	1 (11)	2 (22)
Recent surgery			
None in the 4 weeks prior to COVID-19 diagnosis	811	411 (51)	359 (44)

	Total, n	Hospitalized, n (%)	Ever needed supplemental oxygen, n (%)
Yes	32	19 (59)	15 (47)
Unknown	42	23 (55)	20 (48)
Missing	43	13 (30)	11 (26)
Treatment of COVID-19			
Hydroxychloroquine alone	89	78 (88)	71 (80)
Azithromycin alone	93	53 (57)	50 (54)
Both	181	148 (82)	141 (78)
Neither	486	158 (33)	116 (24)
Unknown	22	9 (41)	8 (36)
Missing	57	4 (7)	4 (7)

Supplementary Table S9: Post-hoc logistic regression analysis of composite outcome. Bivariable and multivariable regression models of prognostic factors associated with a composite of severe illness (death, severe illness requiring hospitalization, intensive care unit admission, and/or mechanical ventilation). Goodness of fit for the fully adjusted model: C-statistic=0·80; 95% CI, 0·77-0·83.

	Composite/Total[1], No. (%)	Bivariable OR (95% CI)	Multivariable pAOR (95% CI)
Age[2]	242/928 (26)	1·6 (1·42-1·81)	1·99 (1·48-2·68)
Sex			
Female	101/459 (22)	Reference	Reference
Male	141/468 (30)	1·53 (1·14-2·06)	1·23 (0·86-1·76)
Race			
Non-Hispanic White	126/460 (27)	Reference	Reference
Non-Hispanic Black	42/148 (28)	1·02 (0·68-1·54)	1·03 (0·63-1·68)
Hispanic	32/150 (21)	0·71 (0·46-1·11)	0·86 (0·5-1·49)
Other/Unknown	37/128 (29)	1·08 (0·7-1·67)	1·78 (1·01-3·15)
Region of patient residence[3]			
US-Northeast	107/375 (29)	Reference	Reference
US-Midwest	55/203 (27)	0·93 (0·64-1·36)	0·83 (0·51-1·34)
US-South	30/117 (26)	0·86 (0·54-1·38)	0·87 (0·49-1·53)
US-West	27/116 (23)	0·76 (0·47-1·23)	1·02 (0·56-1·88)
Canada	11/49 (22)	0·73 (0·36-1·47)	0·25 (0·1-0·64)
Spain	12/68 (18)	0·54 (0·28-1·04)	0·45 (0·2-1·04)
Smoking status			
Never smoked	99/469 (21)	Reference	Reference
Former smoker	116/326 (36)	2·02 (1·47-2·77)	1·41 (0·97-2·07)
Current smoker	8/43 (19)	0·86 (0·39-1·92)	0·56 (0·22-1·44)
Unknown	15/57 (26)	1·28 (0·68-2·41)	1·15 (0·55-2·43)
Obesity			
Not specified	190/720 (26)	Reference	Reference
Obese	49/172 (28)	1·12 (0·77-1·62)	1·26 (0·8-1·97)
No. of comorbidities[4]			
Zero	12/132 (9)	Reference	Reference
One	31/202 (15)	1·82 (0·9-3·69)	1·1 (0·49-2·44)
Two	79/231 (34)	5·05 (2·64-9·68)	2·95 (1·39-6·23)
Three	37/117 (32)	4·7 (2·32-9·51)	1·8 (0·79-4·12)
Four+	71/192 (37)	5·79 (2·99-11·21)	2·49 (1·14-5·48)
Unknown	8/23 (35)	5·24 (1·85-14·86)	3·12 (0·94-10·32)
Type of malignancy			
Solid tumor	151/654 (23)	Reference	Reference
Hematologic malignancy	58/167 (35)	1·77 (1·23-2·56)	2·02 (1·27-3·21)

	Composite/Total[1], No. (%)	Bivariable OR (95% CI)	Multivariable pAOR (95% CI)
Multiple cancers	33/107 (31)	1·49 (0·95-2·33)	1·08 (0·64-1·83)
Cancer status			
Remission/NED	95/422 (23)	Reference	Reference
Present, stable or responding to treatment	80/294 (27)	1·26 (0·89-1·77)	1·38 (0·86-2·21)
Present, progressing on treatment	36/102 (35)	1·8 (1·13-2·87)	2·41 (1·32-4·38)
Unknown	23/59 (39)	2·07 (1·17-3·68)	2·97 (1·48-5·97)
ECOG performance status			
0/1	135/614 (22)	Reference	Reference
2	31/72 (43)	2·69 (1·62-4·46)	1·94 (1·07-3·51)
3/4	22/46 (48)	3·3 (1·8-6·08)	2·48 (1·21-5·09)
Unknown	51/167 (31)	1·57 (1·08-2·3)	1·11 (0·7-1·78)
Type of anti-cancer therapy[5]			
None in the 4 weeks prior to COVID-19 diagnosis	156/553 (28)	Reference	Reference
Non-cytotoxic therapy	50/206 (24)	0·82 (0·56-1·18)	0·76 (0·48-1·21)
Cytotoxic systemic therapy	35/160 (22)	0·71 (0·47-1·08)	0·72 (0·42-1·24)
Unknown	1/9 (11)	0·32 (0·04-2·56)	0·54 (0·06-5·32)
Recent surgery[6]			
None in the 4 weeks prior to COVID-19 diagnosis	212/811 (26)	Reference	Reference
Yes	12/32 (38)	1·67 (0·8-3·51)	1·85 (0·8-4·31)
Unknown	14/42 (33)	1·39 (0·72-2·69)	1·07 (0·47-2·44)
Treatment of COVID-19			
Hydroxychloroquine alone	32/89 (36)	2·73 (1·66-4·48)	2·06 (1·18-3·6)
Azithromycin alone	26/93 (28)	1·98 (1·18-3·3)	2·08 (1·16-3·75)
Both	86/181 (48)	4·44 (3·03-6·5)	6·06 (3·78-9·71)
Neither	80/486 (16)	Reference	Reference
Unknown	8/22 (36)	2·78 (1·12-6·89)	1·93 (0·71-5·23)

[1]Total may not add to 100% for all characteristics, due to missingness.
[2]Age 90+ transformed into exact age of 90 for modeling purposes. Reported risks are per decade.
[3]US regions are census-tract defined.
[4]Defined as comorbidities (other than cancer) that require active treatment.
[5]Defined as receipt of therapy within 4 weeks of COVID-19 diagnosis.
[6]Includes any surgery, including cancer-specific surgeries, performed within 4 weeks of COVID-19 diagnosis.